



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065408	Epirubicin Hydrochloride (HCl) Injection, 150 milligrams (mg)/75 milliliters (mL) (2 mg/mL), 10	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047

Application No.	Drug	Applicant
	mg/5 mL (2 mg/mL), 50 mg/25 mL (2 mg/mL), and 200 mg/100 mL (2 mg/mL)	
ANDA 065411	Epirubicin HCl Injection, 200 mg/100 mL (2 mg/mL) and 50 mg/25 mL (2 mg/mL)	Do.
ANDA 065440	Idarubicin HCl Injection, 1 mg/mL	Do.
ANDA 077790	Fludarabine Phosphate for Injection, 50 mg/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
ANDA 091008	Gabapentin Capsules, 100 mg, 300 mg, and 400 mg	Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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